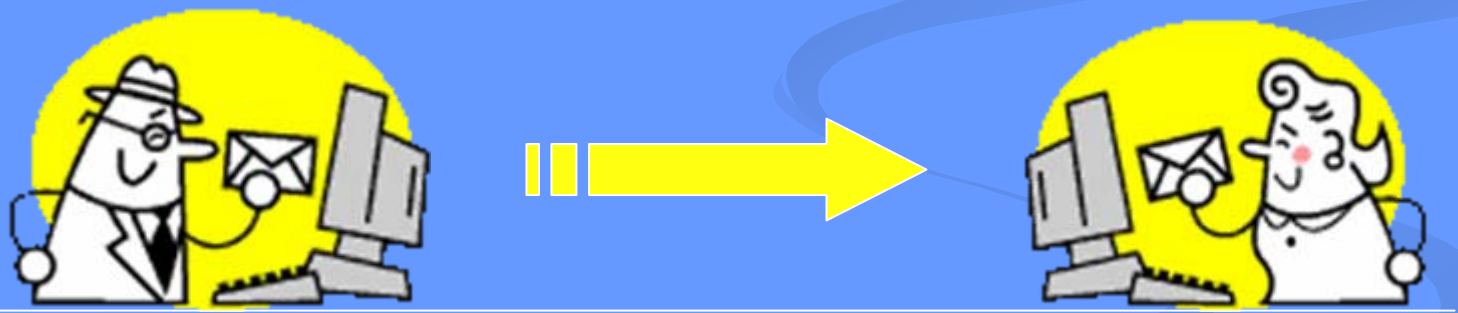
National Program of Cancer Registries - Modeling Electronic Reporting Project (NPCR-MERP)

ePath Reporting Pilot Project

September 27, 2006



Wendy Scharber, Northrup Grumman
Sandy Thames, CDC
Sanjeev Baral, Northrop Grumman

History of ELR in Infectious Disease

- PHIN/NEDSS have been working on electronic laboratory reporting (ELR) from national labs for infectious diseases for years
- PHIN/NEDSS have established relationships and implemented ELR transmissions with LabCorp, Quest, and Mayo
- LabCorp is currently submitting HL7 messages to 25 states
- LabCorp has one mainframe in NC that contains data reported from all states with a LabCorp presence – one point of contact

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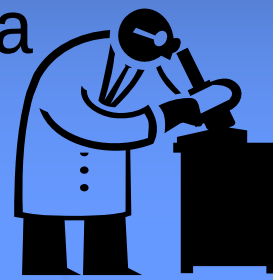
History of Pathology Reporting in Cancer Registry

- Most cancer diagnoses (up to 90%) rely on a positive microscopic finding documented on pathology reports.



- Historically, path reports have been received in paper format, if received at all.

- States have worked with local path labs to get data any way they can.

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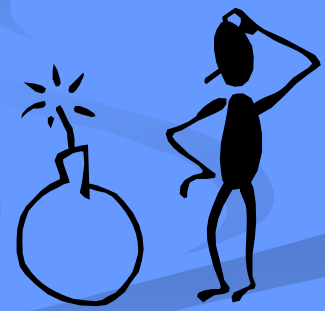
History of Pathology Reporting in Cancer Registry (con't)

- Challenges
  - Legal Authority
    - Mandatory / Voluntary
    - All reports / Only Cancer related reports
  - Responsibilities
    - File creation
      - (LIS) vendor / Path Lab It / Registry IT
    - File transfer
      - Vendor / Registry
      - HL7 / ascii pipe-delimited file
      - Who pays



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History of Pathology Reporting in Cancer Registry (con't)

- Until recently, no standard format for receiving ePath data from labs

Use of HL7 in E-Path reporting "*enables a consistent exchange of disease data between public health partners*" - as defined by the Public Health Information Network (PHIN).

History of Pathology Reporting in Cancer Registry (con't)

- NAACCR formed a workgroup to develop a standard HL7 message for E-Path
  - NEDSS ELR Implementation Guide used as a template

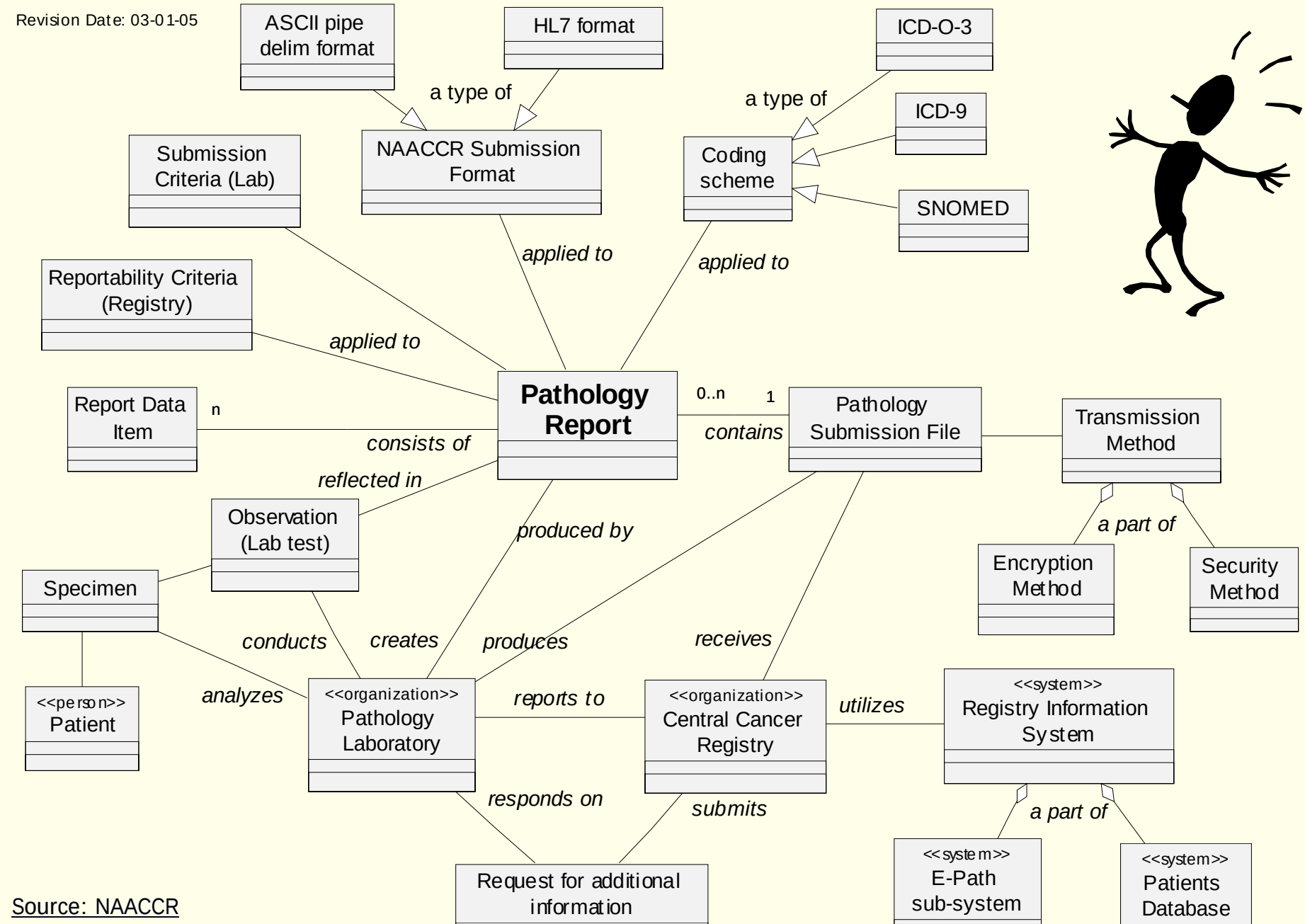
HL7 Implementation Guide for E-Path Reporting

HL7 Message Layout Standard
Data Item Requirements

E-Path Reporting Process Guide

Step-by-step processes description
Business rules
UML activity and domain diagrams

E-Path Reporting: Domain Diagram



Source: NAACCR

P1. Prepare Report - Main Scenario

3. Laboratory adds data items to the “completed” Pathology Report according to requirements for the reporting to Registry.
   - Related business rules: BR07, BR08.

BR	Business Rule statement	Purpose	Remarks / Links
07	**All data items listed as “Required” (R) or “Required if available” (R*) must be included in the submitted reports to Registry.** ***Standards for Cancer Registries Volume V: NAACCR Pathology Laboratory Implementation Version 2.0 (November 2005)***	**Ensure the proper scope of reporting**	**Modifications to the required data item list may be agreed upon by the Registry and the Laboratory.**
08	**Data items that will be submitted using laboratory specific codes must have a codes and definitions table provided to the Registry.**	**Ensure accurate processing of coded data items.**	

P1. Prepare Report - Main Scenario

4. Laboratory formats report according to NAACCR record layout standard
   - Related business rule BR09

BR	Business Rule statement	Purpose	Remarks / Links
09	**One of the two NAACCR E-Path Layout Structures must be used:** **•HL7 Layout (pipe delimited format) - *preferred*** **•ASCII Layout (pipe delimited format)** **Reference: *Standards for Cancer Registries Volume V: NAACCR Pathology Laboratory Implementation Vers 2.0***	**Achieve uniformity and consistency**	**Note: Given the nature of the HL7 message with multiple notations and segments, conformance testing is particularly important to ascertain that the format conforms to the required messaging standard**

5. Lab gathers all reports into a single submission file.
   - Process ends

BR	Business Rule statement	Purpose	Remarks / Links
04	**Laboratory may conduct a preliminary screening of Pathology Reports for relevancy to cancer registration, reducing volume of reporting to Registry.**	**Satisfy privacy-related restrictions and/or restrictions related to Registry's infrastructure.**	**This is an alternative to BR03. Determined mutually by Registry and Laboratory.**
11	**Laboratories that are not sending 100% of the pathology reports must use eligibility criteria established by a recognized cancer registry source.** 	**Ensure completeness of reporting**	***Automated* eligibility criteria include:** **•NAACCR Search Term List** **•SNOMED Codes: 80000 – 99999** **•SEER ICD-O-3 Selection Criteria** **•Others: ICD-9, ICD-10, ICD-O-3, Pathologist indicator.** ***Manual* determination of eligibility by Laboratory personnel (pathologist or other qualified personnel).**

P2. Transmit Report - Main Scenario

1. Laboratory sends Pathology Submission File via a secure connection to Registry.
   - Related business rules: BR31.

BR	Business Rule statement	Purpose	Remarks / Links
31	**File must be transmitted via secure connection (encrypted), using appropriate network protocols.**	**Ensure confidentia-lity**	**Secure connection implies digital-cert and HTTPS.** **If the receiving server uses a digital-cert and HTTPS protocol, then the submission file or the individual lab reports record from the lab does not need to be encrypted. The receiving server's digital-cert and HTTPS protocol handles this.**

Process diagram – Prepare Report (Pathology Lab)

Revision 02-22-05

Process Description

Business Preconditions:
a. Laboratory completed assessment process and is ready for the E-path reporting to Registry.

1. The process starts when Pathology Report is signed in Laboratory as "completed".

2. Laboratory allocates Pathology Report for submission to Registry

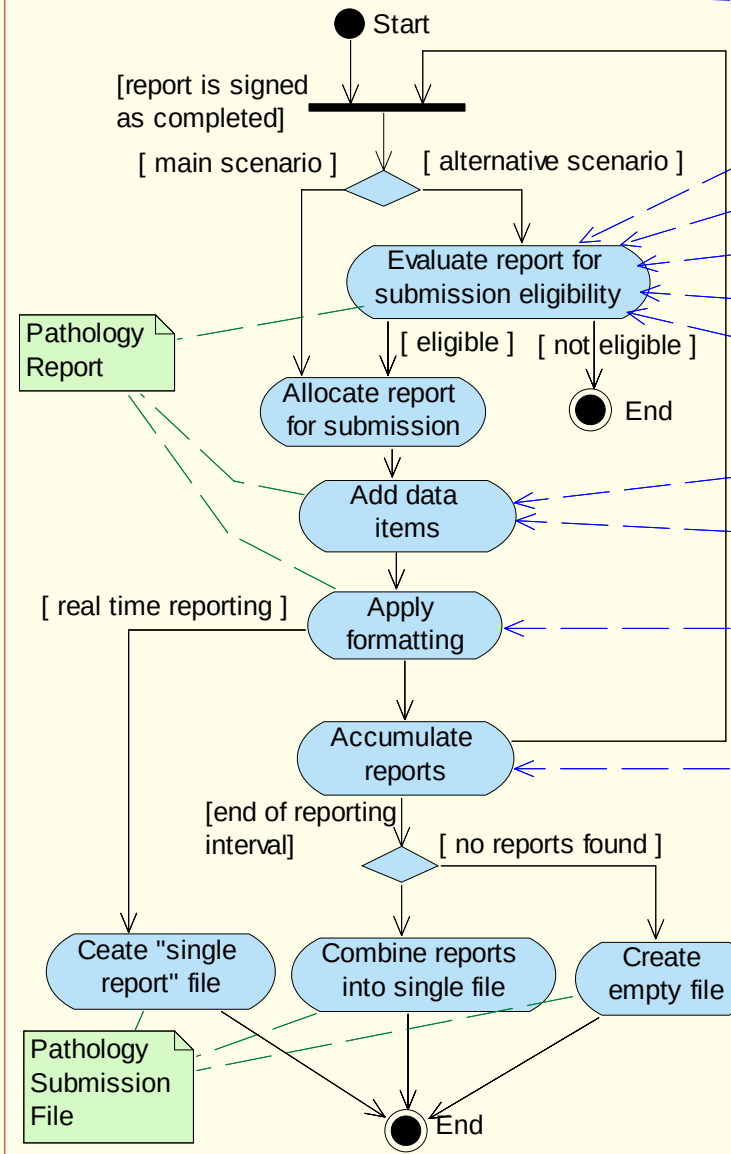
3. Laboratory adds certain data items to the "completed" Pathology Report according to requirements for the reporting to Registry.

4. Laboratory formats resulting Report according to NAACCR record layout standards.

Laboratory repeats steps 2-4 for each Pathology Report, accumulating reports allocated for submission to Registry, until the end of the selected time interval for reporting (unless a real time reporting method is selected).

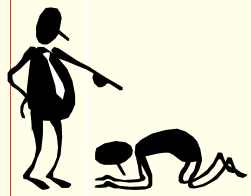
5. Laboratory combines reportable Pathology Reports into a single Pathology Submission File.
Process ends.

Process Diagram



Business Rules

BR01
BR02
BR03
BR04
BR05
BR06
BR11
BR07
BR08
BR09
BR12
BR10



Source: NAACCR

Process diagram – Process Report (Registry)

Revision:04-02-05

Process Description

Business Preconditions
1. Pathology Submission File successfully transmitted from the Laboratory to Registry.

1. The process begins at the end of the selected time interval for processing of received Pathology Submission Files.

2. Registry validates each Pathology Report within Pathology Submission File(s) for presence of report's number and report's text.

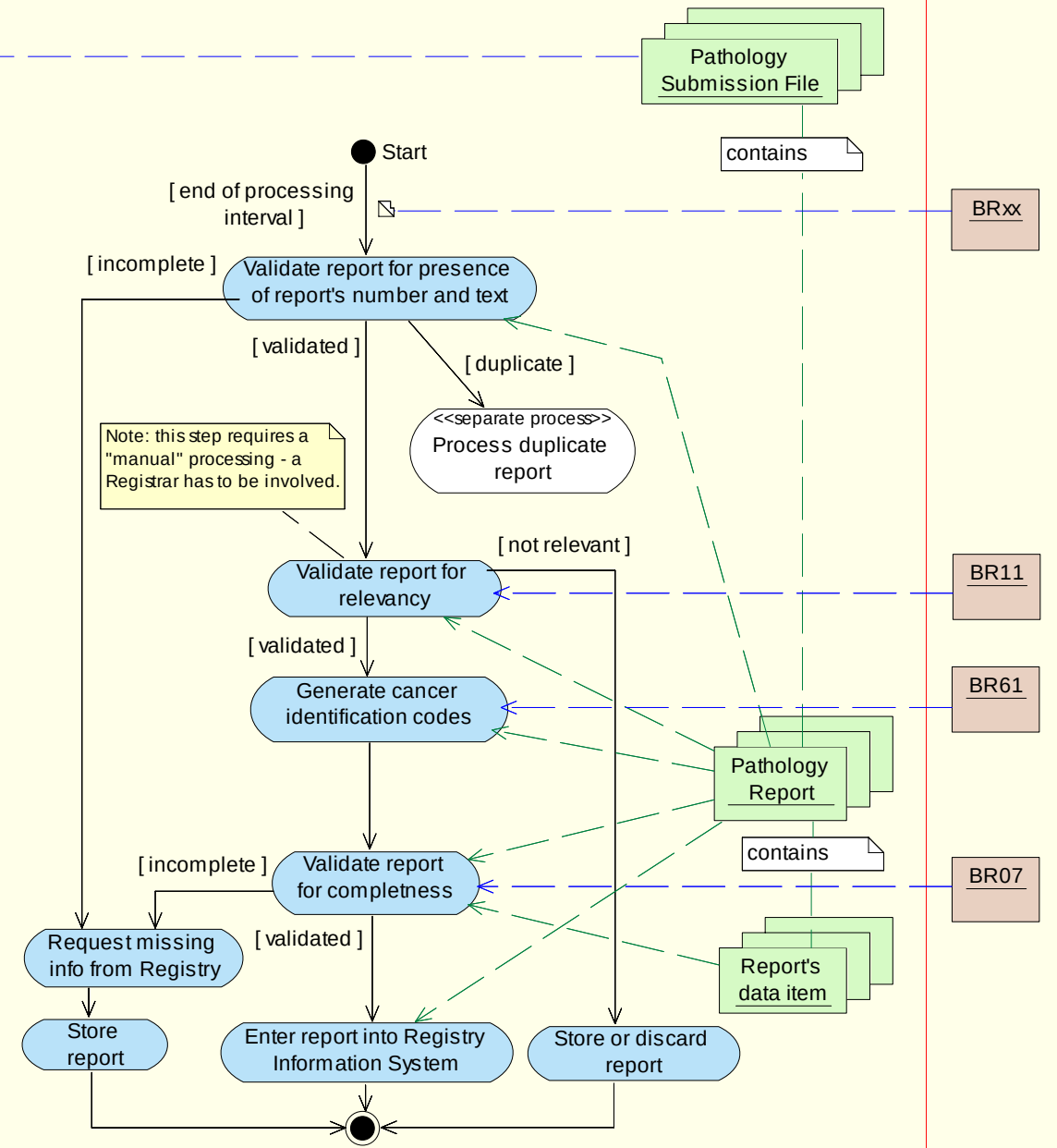
3. Registry validates each Pathology Report within Pathology Submission File(s) for relevancy to cancer registration.

4. Registry generates appropriate cancer identification codes for Pathology Report.

5. Registry validates Pathology Report for completeness, to make sure that a minimum set of required data items is present.

6. Registry enters Pathology Report into the Registry Information System. Process ends.

Process Diagram



Business Rules

Source: NAACCR

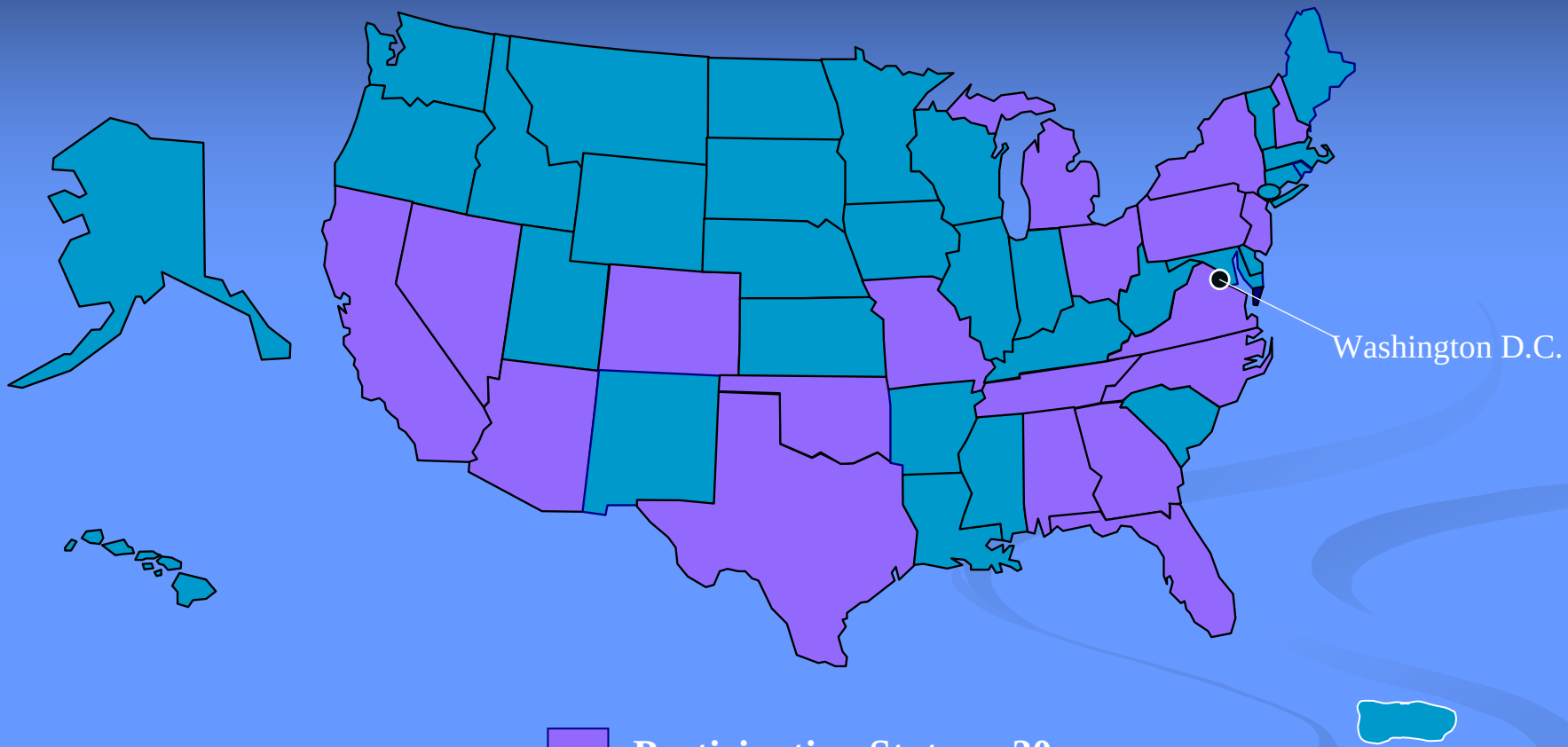
ePath Reporting Pilot Project Objectives

- Implement one standard ePath reporting process that will meet needs of all states
  - Test and document the implementation of ePath reporting from a national laboratory to central cancer registries
  - Adopt and/or develop software needed to successfully implement ePath reporting
    - Evaluate use of the PHIN/NEDSS architecture/tools
  - Provide guidance to central cancer registries and path labs on implementation requirements for ePath reporting
    - Tools and lessons learned freely available

Advantages of pilot project

- One voice working with the laboratory
  - ensures that the lab receives a consistent message
  - Minimizes the need to accommodate individual state nuances that will overburden the lab
- Will build momentum to work with other national labs on implementation
- Make better use of resources by utilizing existing PHIN/NEDSS architecture/tools
  - Don’t re-invent the paper clip

Participating State Cancer Registries in ePath Pilot Project with LabCorp



Participating States – 20
AL, AZ, CA, CO, FL, GA, MD, MI, MO, NV, NH, NJ, NY, NC, OH, OK, PA, TN, TX, VA

Pilot Project Activities

- Test implementation of NAACCR E-Path guides
  - LabCorp will develop an HL7 message consistent with NAACCR Guide
  - CDC will test and validate HL7 message from LabCorp
- Test PHINMS for secure transmission of messages
- Identify and test existing data mapping software – map data from HL7 to standard NAACCR ePath file format (such as NEDSS Messaging Subsystem)

Pilot Project Activity Status

- Test implementation of NAACCR E-Path guides
  - Message Development
    - Ordering Provider requirements and placement in HL7
  - Availability of data items
    - Patient ID not always available
    - Pathologist Name is not a discrete data item (embedded in text)
    - LOINC codes not always available
  - Case/Report Selection
    - Documentation needed to identify reports to include for each state's registry
      - Patient address vs. physician address vs. ??

Findings have been forwarded to NAACCR E-path workgroup

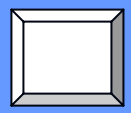
Pilot Project Activity Status

- LabCorp will develop an HL7 message consistent with NAACCR Guide
- CDC will test and validate HL7 message from LabCorp

Valid HL7 message created that meets the NAACCR HL7 Implementation and Reporting Process Guidelines criteria.

Pilot Project Activity Status

- Test PHINMS for secure transmission of messages
  - Participating states have contacted PHIN MS Deployment Team to install PHIN MS or to work with their State PHIN/NEDSS Coordinator
    - 10 states already have PHIN MS installed
    - 4 states have requested the PHIN MS install
    - 5 states plan to request the PHIN MS install
    - 1 state will not be able to use PHIN MS

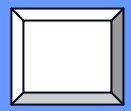


HL7 Message transferred via PHIN-MS

Pilot Project Activity Status

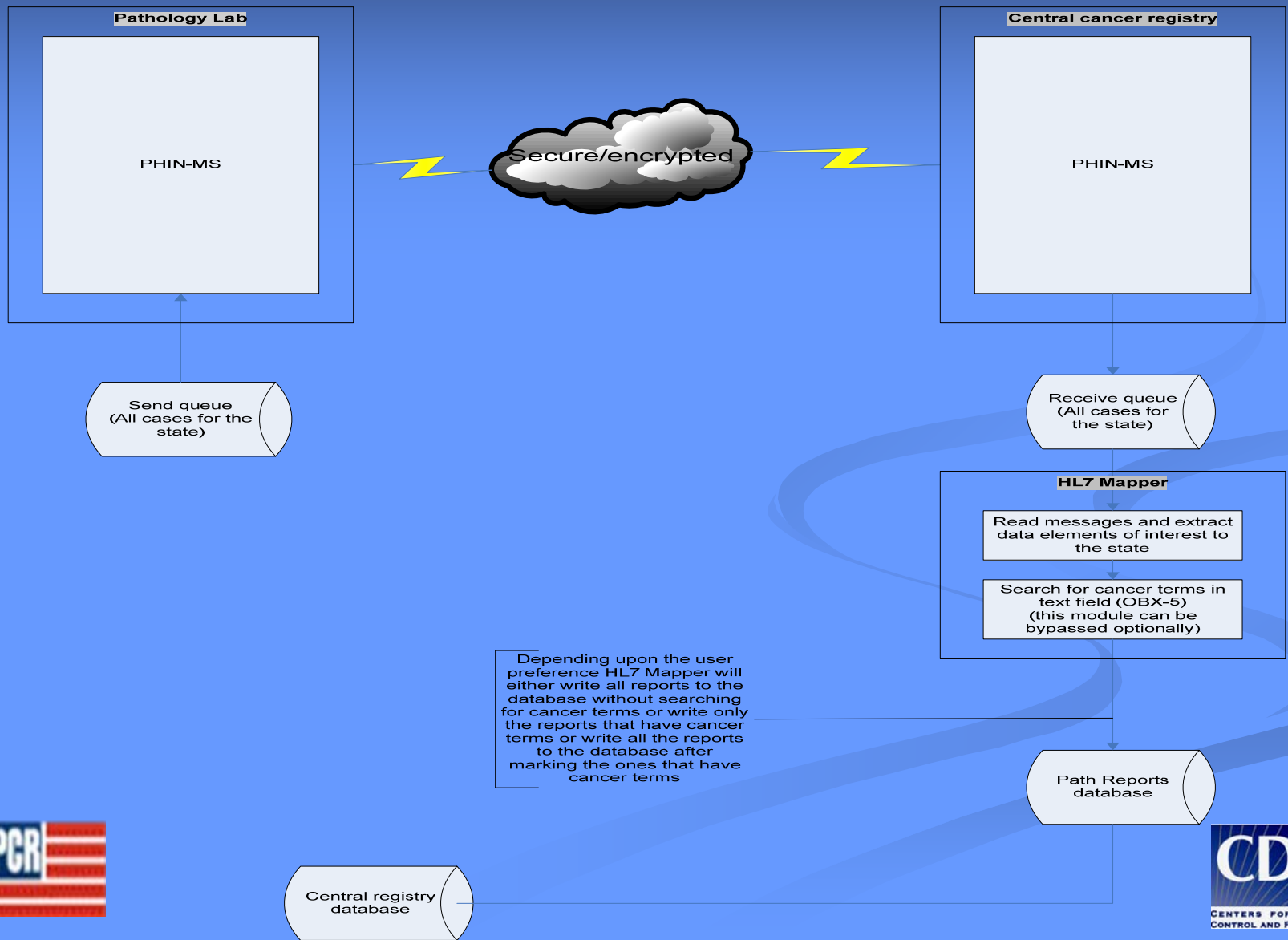
- Identify and test existing data mapping software – map data from HL7 to standard NAACCR ePath file format (such as NEDSS Messaging Subsystem)

HL7 Mapper developed

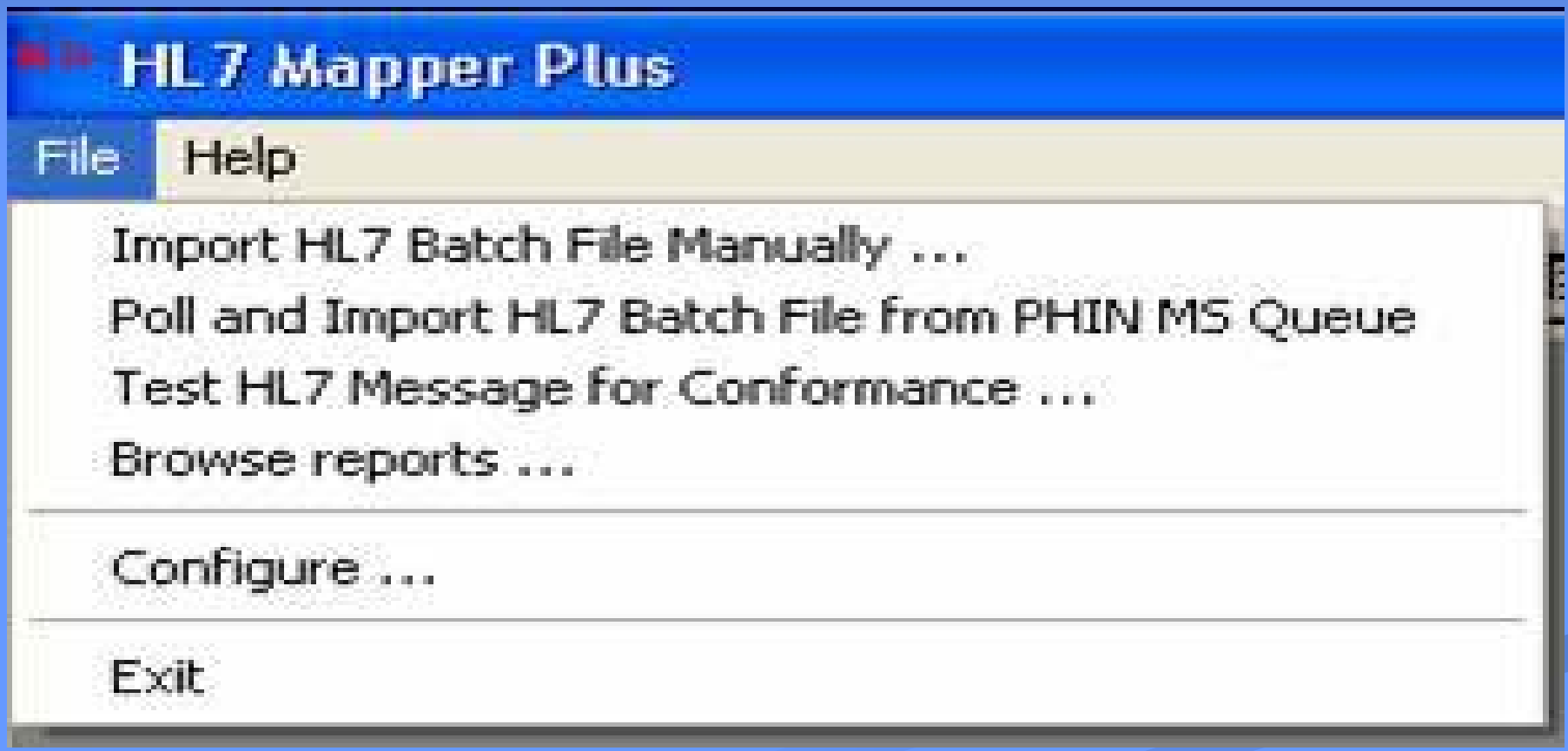


HL7 Mapper Implemented

Data flow of messages



NPCR-MERP HL7 Mapper Plus



NPRC-MERP HL7 Mapper Plus (contd.) HL7 Message

ormatted Report | HL7 Message | Errors

```
MSH|^~\&|LABCORP-CORP|LABCORP^34D0655059^CLIA|FLDOH|FL|200605081100|FL005|ORU^R01|20060508110008051000|P|2.3.1
PID|1||075Y9800060^^^^LabCorp Information Systems&TESTING&CLIA&954954954||TEST^ABCDEFGHI^ABCDEFGHIJKLMNO||19640407|F||U|DEL BOCA VISTA
CONDOMINIUM^^MIAMI^FL^33138||^^^^000^0000000||||||954954954
ORC|RE||075Y9800060|||||||||||||||||FRIENDLY NURSING HOME|3060 S CHURCH ST. INTEGON BLDG^^PASADENA^CA^911235820|^^^^336^5845171||
NK1|1|TEST^ABCDEFGHI^A^||DEL BOCA VISTA CONDOMINIUM^^MIAMI^FL^33138^|^^^^000^0000000|
OBR|1||075Y9800060|^^^500918^Pathology Report^L|||20060316|||||||200603161514|||^^^^336^5845171||||336^222^7566^|||F||||||||||||||||||||
OBX|1|ST|^^^500920^.^L||BIOPSY, SKIN OF LEFT SHOULDER||||||F|||2006031615504 2|TESTING^LabCorp Information Systems^CLIA|||
OBX|2|ST|^^^500943^.^L||702.0 ; Actinic keratosis||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
OBX|3|ST|^^^500923^.^L||History of sunburns x 20 years.||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
OBX|4|ST|^^^500927^.^L||BIOPSY, SKIN OF LEFT SHOULDER:MALIGNANT MELANOMA, SUPERFICIAL SPREADING TYPE.CLARK LEVEL: IIBRESLOW
THICKNESS: 0.01 MMMITOTIC FIGURES/MM SQUARED: 1ULCERATION: YREGRESSION: NLYMPHATIC INVASION: NPERINEURAL INVASION:
NMICROSCOPIC SATELLITOSIS: NTUMOR-INFILTRATING LYMPHOCYTES: NASSOCIATED MELANOCYTIC NEVUS: YPREDOMINANT CYTOLOGY:
EPITHELIOID.SURGICAL MARGINS: CLEAR.BCC/03/16/2006||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
OBX|5|ST|^^^500929^.^L|||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
OBX|6|ST|^^^500930^.^L||1 Container(s), formalin-filled, labeled with patient identification.BIOPSY, SKIN OF LEFT SHOULDER:1 shave biopsy of tan skin measuring
0.3 x 0.3 x 0.3 cm. On thesurface is a polypoid brown lesion measuring 0.1x 0.2 cm. Thespecimen is inked, bisected and submitted in cassette(s)
1./SMB/SMB||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
OBX|7|ST|^^^500940^.^L||172.6||||||F|||20060316155042|TESTING^LabCorp Information Systems^CLIA|||
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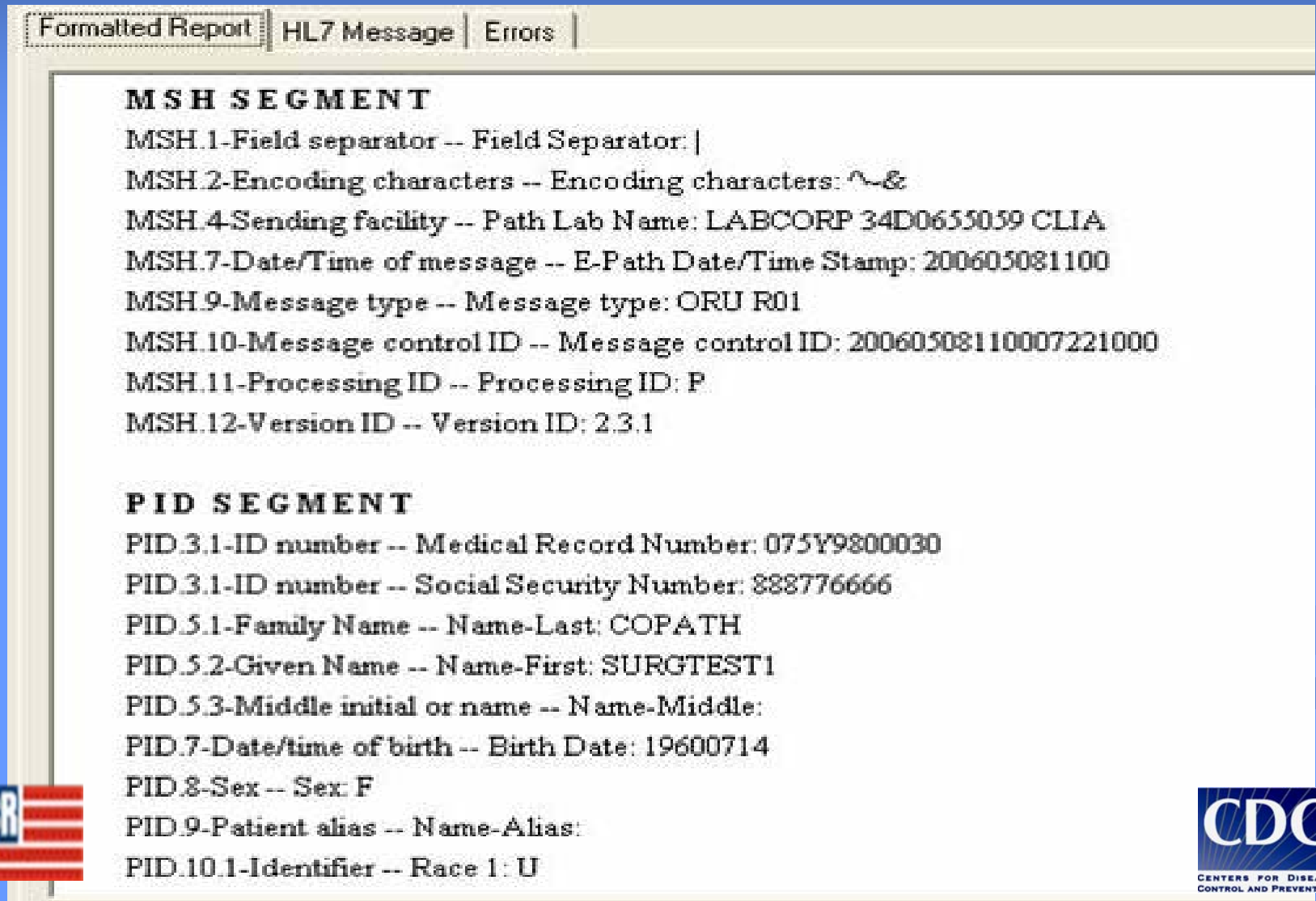
NPRC-MERP HL7 Mapper Plus (contd.) Formatted Report



NPRC-MERP HL7 Mapper Plus (contd.) Error Report

ormatted Report | HL7 Message | Errors

MessageID	Message Control ID (HL7)	Sending Facility	Message
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item PID.22
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBR.22
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBR.25
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.1
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.2
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.3
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.1
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.2
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.3
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.1
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.2
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.3
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.1
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.2
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.3
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.1
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.2
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.3.3
3	20060508110008051000	LABCORP^34D0655059^CLIA	Missing required data item OBX.6.1

NPRC-MERP HL7 Mapper Plus (contd.) Pathology Report

ormatted Report | HL7 Message | Errors

Pathology Final Diagnosis

Pathology Text Diagnosis

BIOPSY, SKIN OF LEFT SHOULDER
702.0 ; Actinic keratosis
History of sunburns x 20 years.
BIOPSY, SKIN OF LEFT SHOULDER:MALIGNANT MELANOMA, SUPERFICIAL SPREADING TYPE.CLARK LEVEL: IIBRESLOW THICKNESS: 0.01 MMMITOTIC FIGURES/MM SQUARED: 1ULCERATION: YREGRESSION: NLYMPHATIC INVASION: NPERINEURAL INVASION: NMICROSCOPIC SATELLITOSIS: NTUMOR-INFILTRATING LYMPHOCYTES: NASSOCIATED MELANOCYTIC NEVUS: YPREDOMINANT CYTOLOGY: EPITHELIOID.SURGICAL MARGINS: CLEAR.BCC/03/16/2006

1 Container(s), formalin-filled, labeled with patient identification.BIOPSY, SKIN OF LEFT SHOULDER:1 shave biopsy of tan skin measuring 0.3 x 0.3 x 0.3 cm. On thesurface is a polypoid brown lesion measuring 0.1x 0.2 cm. Thespecimen is inked, bisected and submitted in cassette(s) 1./SMB/SMB
172.6

Pathology Clinical History

Pathology Nature of Specimen

Pathology Gross Pathology

Pathology Micro Pathology

Does not always work ☹

NPRC-MERP HL7 Mapper Plus (contd.) Report Selection

Documents Reference

- NAACCR web site: www. naaccr.org
  - *Standards for Cancer Registries Volume V: NAACCR Pathology Laboratory Implementation Version 2.0 (November 2005)*
  - Electronic Pathology Reporting Guidelines – Draft
    - December, 2006
- NPCR-MERP web site:
  - www.cdc.gov/cancer/npcr/tools/merp/

Contact Information

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  - Northrup Grumman – CDC Contractor
  - Email: sbaral@cdc.gov

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